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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,085	03/02/2004	Steve Koh	A04P1019US01	4881

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PACESETTER, INC.
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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/792,085	KOH, STEVE	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11* is/are allowed.

6)☒ Claim(s) *1,2,6,7 and 12* is/are rejected.

7)☒ Claim(s) *3-5,8-10 and 13-15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Objections

Claims 3, 7 and 9 are objected to because of the following informalities:

On line 7 of claim 3, "CSR, " should be replaced with "CSR, and";

On line 2 of claim 7, "severity CHF" should be replaced with "severity of CHF";

On line 2 of claim 9, "wherein should be replaced with "further comprising";

On line 2 of claim 9, "CSR-CHF" should be replaced with "CSR caused by CHF (CSR-CHF)";

On line 2 of claim 9, "comprises" should be replaced with "by".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 7, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,641,542 to Cho et al. Cho teaches a method and system for evaluating the severity of congestive heart failure (CHF) within a patient using an implanted medical device 320 wherein the patient also exhibits Cheyne-Stokes Respiration (CSR) caused by CHF. A CSR periodicity determination unit operates to

determine a periodicity associated with CSR in the patient is detected (col. 8, lines 61-67 of Cho). A CSR periodicity-based CHF evaluation unit operates to evaluate the severity of CHF within the patient based on the periodicity (col. 9, lines 45-53 of Cho).

Regarding claim 2, the periodicity is detected to detect a time period representative of periodic breathing during CSR (col. 8, lines 61-64; col. 9, lines 45-47 of Cho).

Regarding claim 6, it is determined whether the patient is asleep (col. 11, lines 11-22 of Cho).

Regarding claim 7, therapy may be delivered to the patient based on the severity of the CHF (col. 9, lines 45-67 of Cho).

Allowable Subject Matter

Claim 11 is allowed.

Claims 3-5, 8-10, and 13-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 3 and 4, the prior art of record fails to teach or fairly suggest a method for evaluating the severity of congestive heart failure (CHF) within a patient using an implanted medical device wherein the patient also exhibits Cheyne-Stokes Respiration (CSR) caused by CHF, wherein a time period associated with CSR is detected for the patient by determining the average duration of periods of apnea during

a detected episode of CSR, determining the average duration of periods of breathing between the periods of apnea during CSR, and combining the average duration of periods of apnea with the average duration of periods of breathing, in combination with all of the other limitations of the claims.

Regarding claim 5, the prior art of record fails to teach or fairly suggest a method for evaluating the severity of congestive heart failure (CHF) within a patient using an implanted medical device wherein the patient also exhibits Cheyne-Stokes Respiration (CSR) caused by CHF, wherein the severity of CHF within the patient is determined based on periodicity by comparing the periodicity associated with the CSR against a set of values indicative of the severity of CHF, in combination with all of the other limitations of the claim.

Regarding claims 8 and 14, the prior art of record fails to teach or fairly suggest a system or method for evaluating the severity of congestive heart failure (CHF) within a patient using an implanted medical device wherein the patient also exhibits Cheyne-Stokes Respiration (CSR) caused by CHF wherein an implantable drug pump is provided and the dosage or the type of drug is selected based on the degree of severity of CHF, in combination with all of the other limitations of the claim.

Regarding claims 9 and 15, the prior art of record fails to teach or fairly suggest a method or system for evaluating the severity of congestive heart failure (CHF) within a patient using an implanted medical device wherein the patient also exhibits Cheyne-Stokes Respiration (CSR) caused by CHF, wherein the aggressiveness of overdrive therapy is adjusted based on the degree of severity of CHF, in combination with all of

the other limitations of the claim. While Cho teaches a pacing pulse generator and administering overdrive pacing as a possible therapy (col. 10, lines 13-41 of Cho), there is no suggestion in Cho to adjust the aggressiveness of the overdrive therapy based on the degree of severity of CHF.

Regarding claim 10, the prior art of record fails to teach or fairly suggest a method for evaluating the severity of congestive heart failure (CHF) within a patient using an implanted medical device wherein the patient also exhibits Cheyne-Stokes Respiration (CSR) caused by CHF wherein it is verified that the CSR is caused by CHF and not central sleep apnea (CSA) based on the periodicity, in combination with all of the other limitations of the claim.

Regarding claim 11, the prior art of record fails to teach or fairly suggest a method for evaluating the severity of congestive heart failure (CHF) within a patient using an implanted medical device wherein the patient also exhibits Cheyne-Stokes Respiration (CSR) caused by CHF comprising detecting changes over time in the periodicity associated with CSR and detecting one of a progression or regression of CHF within the patient over time based on the changes in periodicity, wherein an increase in a time period of CSR corresponds to a progression of CHF, in combination with all of the other limitations of the claim. US Patent No. 6,641,542 to Cho tracks a periodicity associated with CSR for the patient and detecting progression of CHF within the patient over time based on the periodicity (col. 8, lines 61-66; col. 9, lines 45-47 of Cho). However, Cho lacks detecting changes over time in the periodicity and the detection of progression is based on a single value or average value of periodicity,

rather than on changes in periodicity. US Patent No. 6,454,719 to Greenhut teaches detecting one of a progression or a regression of CHF within the patient based on changes in periodicity, wherein the periodicity is related to respiration (col. 10, lines 1-39 of Greenhut). However, Greenhut fails to teach the periodicity being associated with CSR.

Regarding claim 13, the prior art of record fails to teach or fairly suggest a system for evaluating the severity of congestive heart failure (CHF) within a patient using an implanted medical device wherein the patient also exhibits Cheyne-Stokes Respiration (CSR) caused by CHF comprising a CHF therapy controller operative to control delivery of therapy to the patient based on the evaluation of the severity of CHF, in combination with the other limitations of the claim.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent NO. 6,645,153 to Kroll et al.

US Patent NO. 6,459,929 to Hopper et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Patent Examiner
Art Unit 3736

ROBERT L. NASSER
PRIMARY EXAMINER